



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,886	03/30/2001	Martha K. Newell	C1102/7002(HCL)	7558

7590 09/23/2004

Helen C. Lockhart
c/o Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210-2211

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,886	NEWELL ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,25-27,38-41 and 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,25-27,38-41 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6, 8-24, 28-37, and 42-48 are canceled. Claims 7, 25-27, 38-41, and 49 are pending and examined.

Claim Rejections - 35 USC § 112

Claims 26-27 and 39-41 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/22/2003. Applicant's arguments filed 6/17/2004 have been considered but are not deemed persuasive. Applicant's acknowledgment of the inadvertent inclusion of the enablement rejection paragraph for the written description paragraph and that the bulk of the rejection was formed by a rejection under written description is appreciated.

Applicant asserts that it was known that fatty acids and nucleotides could be used to regulate UCP function and that Applicant has recognized that the known compounds could be used to target a molecule in a specific cellular location to regulate metabolic processes of the cell (response page 5); and further asserts that the specification does describe compounds, UCP binding peptides, and UCP antibodies which decrease the activity of UCP on pages 23-25 of the specification as well as commercially available antibodies; and describes the use of dominant-negative cell wall or plasma membrane UCP polypeptides at least on page 32 (response page 6).

Art Unit: 1638

Applicant has not addressed the rejection of an adequate written description for UCP binding peptides, UCP antibodies in general comprising plant cell wall and plant plasma membrane UCP, UCP dominant-negative nucleic acids or UCP encoding nucleic acid sequence other than SEQ ID NO: 1, 3, 5, and 7-12 because the compounds listed on page 23 are nucleotide analogs and the rejection did not cover nucleotides or their analogs; and because applicant has only described commercially available antibodies that have been raised against mitochondrial UCP of a non-plant origin; and because the use of dominant negative proteins or how to make and test for dominant negative proteins does not a description of what they are.

Moreover, the proteins, polynucleotides, nucleotides, and binding peptides and fatty acids have structures that vary greatly and are only defined by a common function. Applicant has not described a common structural feature of the broadly claimed genus of UCP inhibitors that could be correlated with the claimed function of inhibition of UCP expression or activity. See MPEP 2163 and the Revised Written Description Guidelines cited previously, which teach that a demonstration of correlation between a structure and a function is required to adequately describe a broadly claimed genus.

Claims 7, 25-27, 38-41, and 49 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/22/2003. Applicant's arguments filed 6/17/2004 have been considered but are not deemed persuasive.

Art Unit: 1638

Applicant asserts that the specification sets forth working examples showing manipulation of UCP activity present in cellular membranes other than the mitochondrial membrane (response page 8, top of page). Applicant has not shown UCP expression in the cell walls of plants. Applicant has shown UCP expression in the cell wall of *Chlamydomonas reinhardtii*, but *Chlamydomonas reinhardtii* is not a plant but rather an alga. It is well known in the art that *Chlamydomonas reinhardtii* does not have roots, leaves, seeds and that their cell walls do not contain cellulose. Further, Applicant has shown that UCP expression in the cell walls of *Chlamydomonas reinhardtii* functions when a non-photosynthetic energy source is required (specification, end of page 41), but has not correlated decreasing cell wall, plasma membrane, or chloroplast UCP expression with any of the claimed effects of the claimed methods in any plant or in *Chlamydomonas reinhardtii*.

Claims 25-27, 38-41, and 49 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/22/2003. Applicant's arguments filed 6/17/2004 have been considered but are not deemed persuasive.

In Claims 25, 26, 38, 39, and 49, "decreasing the expression or activity of UCP" or "the expression or activity of UCP in the plant cell wall/plasma membrane or chloroplast is decreased" lacks a comparative basis.

Claim Rejections - 35 USC § 102

Claims 7, 25-27, 38- 39, 41, and 49 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kowaltowski A.J. *et al.* FEBS Letters, 1998, Vol. 425; pages 213-216. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/22/2003. Applicant's arguments filed 6/17/2004 have been considered but are not deemed persuasive.

Applicant asserts that Kowaltowski does not anticipate the instant claims of the invention because Kowaltowski does not regulate UCP in membranes other than mitochondrial membranes (response page 9). Applicant is arguing limitations that are not in the claims. The only requirement for performing the methods of the claims is to contact the plant with a UCP inhibitor and since the mitochondrial membrane is a part of a plant and has a plant plasma membrane the Kowaltowski reference does anticipate the claimed invention.

Claim Rejections - 35 USC § 103

Claims 7, 25-27, 38-41, and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kowaltowski A.J. *et al.* FEBS Letters, 1998, Vol. 425; pages 213-216 wherein the choice of antisense as an inhibitor of UCP activity would have been an obvious design choice because antisense inhibition is well known in the art. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/22/2003. Applicant's arguments filed 6/17/2004 have been considered but are not deemed persuasive.

Applicant asserts that the Kowaltowski reference does not contain any suggestion that UCP is present in membranes other than mitochondrial membranes (response page 9). See arguments *supra*.

Art Unit: 1638

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
September 12, 2004

Phuong T. Bui
9/20/04
PHUONG T. BUI
PRIMARY EXAMINER